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October 30, 2020

VIA ECF

Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this brief on behalf of the Plaintiffs in opposition to Defendant Teva's request for leave to modify the ESI Protocol, and to consequently permit Teva to not review hundreds of thousands of documents, or for cost shifting. For the reasons set forth herein, either Teva should be required to complete the required review of all documents identified with the search terms, with no cost shifting, or provide the documents to the Plaintiffs.

Preliminary Statement

The history of this issue demonstrates that the equities all weigh against Teva's application, and in fact support the assessment of sanctions against Teva, which: (1) refused

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to sample and test and collaborate with Plaintiffs in connection with the negotiation of the search terms at the outset, (2) agreed to the Order entering the ESI Protocol, (3) agreed to the Order setting forth the search terms that would be used to identify relevant custodial documents, then (4) months later requested entry of an Order with a modified search terms list to address the allegedly unanticipated costs of the review (because they had failed to sample and test on the front end), which resulted in the entry of an Order modifying the search terms applicable to Teva for the ongoing application of the search terms, then (5) shortly after obtaining Plaintiffs' agreement to narrowed search terms, belatedly demanded the overlay of a TAR review, on top of the already narrowed set of documents per the search terms, to further narrow the scope of documents that they were required review, (6) forced Plaintiffs into a protracted, difficult weeks long negotiation, which resulted in a fully negotiated and agreed to Protocol, which included multiple layers of validation, including the provision of an audit sample of 5000 documents to Plaintiffs, then (7) withdrew its motion for a modification to its Court Ordered obligations and refused to proceed with the fully negotiated TAR protocol **because Teva did not want to take the risk that their agreement to that protocol would be confirmed on the public docket.** Now Teva returns to request relief from its obligations yet again.

Teva's repeated representations to the Court and the Plaintiffs dating back more than a year, which were believed and relied on by all, and Teva's agreement to the entry of Orders establishing the search terms methodology, have to mean something. The only equitable outcome is for the Court to deny the application, give Teva the choice of either complying with its obligation to review the documents identified with the search terms

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with no cost shifting, or producing all documents it chooses not to review to Plaintiffs, and to assess sanctions against Teva for its pattern of conduct on this issue, which has severely prejudiced Plaintiffs.

Teva's Request Should Be Denied

This Court is well aware of the tortured history of Teva's numerous efforts to be excused from compliance with the ESI Protocol and *agreed* Order establishing the search terms to be utilized in collecting the documents to be produced to Plaintiffs. Teva has repeatedly represented that it is seeking to reduce its review costs. But when Teva was given the opportunity to completely flip the search methodology from search terms to TAR, Teva declined – based on a vague, speculative concern about putting the negotiated protocol on the docket. Thus, Teva had the relief it claimed to so desperately need, because Plaintiffs engaged in good faith in a grueling negotiation that yielded a mutually acceptable TAR protocol, and then gave it up apparently based on a national litigation strategy or other undisclosed concerns. Teva cannot fairly be permitted to seek the same relief again, but this time without even involving the Plaintiffs or implementing the protocol that Plaintiffs agreed to.

As a preliminary matter, this application is not the forum to determine the value or utility of the TAR system employed by Teva.¹ Teva touts statistics gleaned from its unilateral application of TAR, with no input from Plaintiffs. The variations between what

¹ Plaintiffs dispute that this version of TAR is a proven system, and have established that the system has not been applied as intended (See: Declaration of Plaintiffs' E-Discovery vendor Jonathan Jaffe, attached hereto as Exhibit A).

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Teva did, and the agreed protocol, are not all entirely clear, but some significant differences are apparent. This begins with the document set at issue. In July, Teva recognized that use of TAR to exclude documents from review would have to start with the entire set of all custodial files, not just the already narrowed search terms set – yet Teva chose not to apply TAR to the entire document set once it withdrew its motion. Teva failed to employ much of the agreed protocol, including the use of the core discovery documents to help educate the system, exclusion of certain categories of documents from TAR review (such as videos, pictures, etc.), gave Plaintiffs zero input into the process including the ability to submit further training documents during the process, gave Plaintiffs no reports on the review (including numbers of documents reviewed and number excluded as non-responsive) as the rolling production proceeded, failed to employ the agreed stopping criteria, failed to preclude email threading, and failed to apply the agreed validation protocol including the provision of 5000 purported “non-responsive” documents to Plaintiffs. (The last version of the protocol negotiated in July 2020 is attached hereto as Exhibit B).

It would be grossly inequitable to rely on the data quoted by Teva, or to give any benefit of the doubt to Teva, since the entire process was tainted. Plaintiffs were locked out of the process so it is not possible for Plaintiffs to respond from a level playing field. That was the purpose of the protocol Plaintiffs negotiated, including the validation, to yield data that the parties could jointly rely on.

As the Court has recognized multiple times, the only fair time to vet such a system would have been last summer when the search methodology was being negotiated, when the parties had time to build an agreement from the ground up – including through the use

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of joint sampling and testing, the use of agreed sets of documents to educate the system, and robust validation with Plaintiffs' input and buy in. When Teva raised this issue in July 2020, the Court emphasized that Teva would need to make Plaintiffs' co-lead counsel "an offer you cannot refuse." July 29, 2020 Transcript 31:16-17 (Exhibit C hereto). This recognized the importance of involving Plaintiffs and taking into account Plaintiffs' concerns. The failure to do so here should be fatal to this application from the start.

The details of the factual background make clear where the equities lie. Teva's mischaracterization of the content and meaning of its statement during a meet in confer in November, 2019 regarding TAR is illustrative of Teva's willingness to twist the facts on this application. (Db at 3, fn. 2). At the November 15, 2019 ESI meeting Plaintiffs' counsel asked Teva if they intended to use any type of TAR. Plaintiffs' counsel's notes reflect the following entry: "Their vendor uses TAR, not for searching, but for review or quality checks. It depends on the review. Not 100% they will use or not use, but is something their vendor has." In other words, Teva told Plaintiffs' counsel that their vendor had TAR capabilities, that they were not going to use it for purposes of searching their documents, and that they were not sure they were or were not going to use it at all. This statement simply stated the obvious, that Teva might, for its own purposes, later utilize TAR – this is something defendants and plaintiffs commonly do, in order to enable them to identify documents for their own work product purposes. This statement was made prior to entry of the above Orders, with no concurrent statement by Teva that it was reserving the right to modify its document review obligations at a much later date, based on a TAR review, and Teva certainly never suggested to the Plaintiffs or the Court that search terms were

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viewed as “the **initial mechanism** to identify a set of documents for review.” (Db at 3, fn.2). If any such suggestion had been made, Plaintiffs would have objected, would have requested that the Order preclude a change in the review and production obligations at a later date, and Plaintiffs would have refused to narrow and likely would have requested expansion of the search terms. If suggested to the Court, the Court most certainly would have questioned such an open-ended, but consequential suggestion.

That short exchange at the November 15, 2019 meeting is the first and only time Teva mentioned the use of TAR, until Teva brought up the issue in *July 2020*. Teva never raised the use of TAR during the negotiation of the original search terms in November-December 2019, and again did not raise the issue during the second negotiation of search terms in April-June 2020. In fact, the Order entered June 24, 2020 modifying the Teva search terms clearly lays out that the entire review process would be based on search terms only. The suggestion that Plaintiffs were somehow on notice of the impending massive proposed change to the search methodology is specious.

In fact, Teva violated the ESI protocol (Exhibit D hereto), which provides at Section II, in relevant part:

The parties agree that they will cooperate in good faith regarding the disclosure and formulation of appropriate search methodology, search terms and protocols, and any TAR/predictive coding **prior to using any such technology** to narrow the pool of collected documents to a set to undergo review for possible production. The parties agree to **meet and confer as early as possible**, to discuss, *inter alia*:

- Search methodology(ies) to be utilized (including but not limited to Boolean searches and technology assisted review/predictive coding);

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- Disclosure and selection of all search terms, including foreign language (e.g., Chinese) and search terms based upon actual terminology used in the producing party's documents;
- Search protocol, including but not limited to the custodial and non-custodial sources to which the search methodology(ies) will be applied; and
- Post-search error sampling and sampling/testing reports.

Despite having agreed to an ESI protocol, search terms, and then a second Order narrowing the search terms, Teva approached Plaintiffs yet again, on July 1, 2020, repeating the concern expressed earlier in 2020 that the cost of the manual document review **that Teva had agreed to, twice**, was unacceptable to Teva. **Teva continued to have only itself to blame since it refused to sample or test before agreeing to the search terms production protocol.**

Teva clearly violated both the letter and the spirit of the ESI protocol by waiting until July 2020 to bring up the issue, and by using their TAR methodology prior to meeting and conferring with Plaintiffs. As Section II clearly provides, “the parties agree to meet and confer *as early as possible*, to discuss . . . [s]earch methodology(ies) to be utilized (including but not limited to . . . technology assisted review/predictive coding).” It is clear that July 2020 is certainly not “as early as possible.” Further, to the extent that Teva argues that it was not using TAR to “narrow the pool of collected documents” per the ESI protocol until this latest Motion, that is simply playing semantic games. There was no reason at all for Teva to have begun using TAR other than to set the stage to narrow the pool of collected documents for purposes of review and production, and Teva's suggestions to the contrary have no credibility. For example, Teva's statement that they did so for Plaintiffs' benefit,

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that they “were utilizing CMML to simply prioritize their review so that Plaintiffs would receive the most relevant documents first,” is a brazen misrepresentation. (Db at 2).

Plaintiffs’ position is fully consistent with the Court’s repeated statements to the parties that one of the most important steps in the litigation was to get the ESI protocol and search terms locked in by Order so that the parties could move on to the next phase of the litigation. The time for Teva to request a layered document review process, with TAR layered upon an already narrowed search terms document set, was **prior to entry of the ESI protocol and search terms Order – which was agreed to by Teva**, not seven months after the search terms were finalized and Ordered.

Teva’s hypocrisy during this process has been notable. In the brief submitted by Teva prior to the July 15, 2020 conference with the Court, Teva complained of the volume of documents and asserted the need to avoid the cost and delay attendant to human review of documents for relevancy, even with the narrowed search terms that Plaintiffs had agreed to (while neglecting to acknowledge that relevancy and privilege review is for the benefit of the Defendants, not the Plaintiffs). However, on questioning by the Court, it was revealed that Teva still intended to have attorneys review every document identified as responsive, obviously content to spend whatever time and effort was needed to try to establish a reason not to produce a document hit by the search terms, and found to be responsive by the CMML application. Teva only intended to dispense with the human review of documents that were coded as unlikely to be responsive, content to let those documents disappear.

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Ultimately, Teva obtained Plaintiffs' agreement to let it use a TAR review, only to then withdraw its application, rather than let the Court decide whether the agreement would have been made public. The suggestion in Teva's brief that this was Plaintiffs' fault is not credible: "Plaintiffs' unreasonable refusal to acknowledge these legal standards forced Teva to withdraw its prior motion, while reserving its rights." (Db at 4, fn 3). The truth is that Plaintiffs were well within their rights, and Teva was unwilling to risk agreeing to the protocol and having it filed on ECF for some unknowable reason since, as set forth below, unreviewed documents are commonly provided to Plaintiffs.

The Case Law Strongly Supports Plaintiffs' Position

There is precedent directly on point. In *Progressive Cas. Ins. Co. v. Delaney*, 2014 WL 3563467, at *11-12 (D. Nev. July 8, 2014) (Exhibit E hereto), the Court refused to allow the defendant to proceed to layer a TAR review on top of a document set already narrowed from 1.8 million pages to 565,000 pages by application of search terms. The case is a playbook for why Teva should be similarly precluded here. First, the Court heavily weighted the producing party's attempt to impose TAR methodology at the last minute, on top of a search term methodology that had already been put in place. The equitable concerns of that Court certainly apply equally or more so here. In addition, Teva acted unilaterally, having cast aside the protocol that Plaintiffs had agreed to – including the application of TAR to the full document set rather than the already narrowed search terms set.

Teva's abandonment of Plaintiffs flies in the face of settled principles requiring cooperation – especially in the context of a heavily litigated MDL: **"The cases which have**

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approved technology assisted review of ESI have required an unprecedented degree of transparency and cooperation among counsel in the review and production of ESI responsive to discovery requests . . . the courts have required the producing party to provide the requesting party with full disclosure about the technology used, the process, and the methodology, including the documents used to ‘train’ the computer.”

Id. at *10 (emphasis added) (citing in part *In re Actos (Piglitazone-Prods. Liab. Lit.)*, No. 6:11-md-2299, slip op. (W.D. La. July 7, 2012)). The Court held that the defendant could not apply TAR to further limit the document set collected with the search terms, and the defendant was ordered to produce every document hit by the search terms, including those that the defendant claimed to be non-responsive. *Id.* at 12. These concerns were being addressed here, this past summer, when the Plaintiffs agreed to a protocol that would give them input, quality control review, and robust validation. But Teva then abandoned that protocol, cynically withdrawing its motion and thereby freeing itself to apply a unilaterally selected process with no Plaintiff input or oversight. It would be quite unfair to reward this tactic.

In fact, contrary to Teva’s representation that no defendant has ever voluntarily allowed plaintiffs access to “non-responsive” documents, that is exactly what is provided for in the 3M MDL.. The TAR protocol filed in that litigation (See attached at Exhibit F) provides: (1) that the plaintiffs are provided the sample set used to train the system (Section 3(c)), (2) the final elusion sample, which is the equivalent of the audit sample provided for in the protocol agreed to here and then jettisoned by Teva, is provided to the plaintiffs (Section 5(b)-(d)), and (3) once the validation is completed the defendant must manually

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review all documents with a classification score exceeding an established threshold OR all of the proposed unreviewed documents must be produced to the plaintiffs (Section 5(g)). Thus, Teva's representations and concerns that potentially "non-responsive" documents are never provided to the plaintiffs are simply incorrect. Moreover, the level of up front involvement by the plaintiffs in 3M was never available to Plaintiffs here due to the belated roll out. This materially devalued the TAR review since critical documents were not included in the process of training of the system.

There is a plethora of decisions that establish the propriety of orders compelling production of documents without a relevance or responsiveness review. The Third Circuit recently denied a mandamus application directed to Judge Rufe's decision directing the production of documents without such review, while including safeguards agreed to by Plaintiffs here including privilege review and clawback, and clawback of unrelated product documents. *In re: Generic Pharmaceuticals Pricing Antitrust Litig.*, No. 16-md-2724, 2019 WL 8106511 (E.D. Pa. 2019) (Exhibit G hereto). **"Defendants shall apply the agreed search terms to the agreed custodial files and may review the identified documents for privilege, but may not withhold prior to production any documents based on relevance or responsiveness."** *Id.* at *1, *mandamus denied*, *In re Actavis Holdco U.S. Inc., et al.*, No. 19-3549, 2019 WL 8437021, at *1 (3d Cir. 2019) (emphasis added) ("district courts have, in some circumstances, ordered the production of documents without a manual relevance review, see, e.g., *Consumer Fin. Prot. Bureau v. Navient Corp.*, No. 3:17-CV-101, 2018 WL 6729794, at *2 (M.D. Pa. Dec. 21, 2018); *UPMC v. Highmark Inc.*, No. 2:12-CV-00692-JFC, 2013 WL 12141530, at *2 (W.D. Pa. Jan. 22, 2013);

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Williams v. Taser Int'l, Inc., No. CIVA 106CV-0051-RWS, 2007 WL 1630875, at *6 (N.D. Ga. June 4, 2007)”) (Exhibit H hereto); *see also Chen-Oster v. Goldman Sachs & Co.*, No. 10 Civ. 6950, 2014 WL 716521, at *1 (S.D.N.Y. Feb. 18, 2014) (“In light of the availability of technology-assisted-review, another model is possible. The parties can simply agree on the search methodology, for example by stipulating to search terms, with the understanding that all documents (except those containing privileged information) shall be produced. This approach essentially elides the search process with substantive determination of relevance and it has the advantage of saving resources for the producing party, which did not conduct a further review for responsiveness.”) (Exhibit I hereto); *Adair v. EQT Prod. Co.*, No. 1:10cv00037, 2012 WL 1965880, at *5 (W.D. Va. May 31, 2012) (Exhibit J hereto), where the court found that the clawback provision included in the protective order, in combination with the agreement to withhold emails between in-house and outside counsel, obviated the need for a review of ESI to protect privileged information. The court also found that the responsiveness of the emails could be ensured through the filtering of emails by custodian, date, and search terms. The court ordered that all emails be treated as confidential in order to protect sensitive business information. The plaintiffs would review documents that hit on key words and inform the court whether the production was over or under inclusive and additional productions could be refined or broadened accordingly; *Adair v. EQT Prod. Co.*, Nos. 1:10CV00037, 1:10CV00041, 2012 WL 2526982, at *4-6 (W.D. Va. June 29, 2012) (Exhibit K hereto), the District Judge affirmed the Magistrate’s order with some modifications, indicating that the magistrate did not order that privileged material be produced and only offered a reasonable resolution to

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narrow the universe of relevant documents and find potentially privileged documents, and that Rule 26 and Rule 502 contemplate such an approach; *Burke v. Ability Ins. Co.*, 291 F.R.D. 343, 356 (D. S.D. May 31, 2013), where the Court ordered the production of documents hit by search terms with no withholding for lack of relevance, stating that “Defendants do not get to pick and choose which documents they think are relevant to [plaintiff’s] claim.”

Another instructive case supporting Plaintiffs’ position is *Rio Tinto PLC v. Vale S.A. et al.*, 306 F.R.D. 125 (S.D.N.Y. 2015). In that case, the parties **agreed** to a TAR protocol, both parties (this was a commercial case) were utilizing the same machine based learning protocol **from the outset**, and the parties agreed to share seed sets of documents, and to allow the requesting party to obtain quality control reports during the reviews. The Court cited to a line of cases requiring collaboration, including involvement of the requesting party in the coding and quality control process. This includes *In re Actos*, No. MDL No. 6:11-md-2299, 2012 WL 7861249 (W.D. La. July 27, 2012), characterized as follows: “the parties’ protocol had ‘experts’ from each side simultaneously reviewing and coding the seed set.” *Rio Tinto PLC*, 306 F.R.D. at 128. (See Also: Jonathan Jaffe Declaration; Exhibit A hereto). The protocol that was negotiated by the parties here, then abandoned by Teva before it unilaterally made up its own process, provided for extensive input from the Plaintiffs, extensive quality control, and robust validation including turning over 5000 purportedly “non-responsive” documents to the Plaintiffs for independent verification – a provision suggested by Teva.

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Another compelling case is *In re Mercedes-Benz Emissions Litig.*, Case No. 2:16-cv-881, 2020 WL 103975 (D.N.J. Jan. 9, 2020) (Exhibit L hereto). *In re Mercedes-Benz*, Judge Cavanaugh made clear that where a defendant chooses to use search terms, and the plaintiffs and the Court rely on and implement that selection, the defendant cannot be permitted to later upend the process and seek to change the methodology when it has buyer's remorse.

Teva cites a series of inapplicable cases that focus on whether a requesting party can compel the producing party to use TAR, when the producing party chooses not to. *See Hyles v. New York City*, No. 10 Civ. 3119, 2016 WL 4077114 (S.D.N.Y. Aug. 1, 2016). That is not this case, and all of that legal discussion in Teva's brief can be disregarded. Similarly, the cases cited by Teva for the proposition that layering of TAR is appropriate do not address facts like those here, with the defendant seeking to impose this condition at the end of the process, rather than per a protocol negotiated and agreed to at the outset. Likewise, the cost-shifting cases cited by Teva do not address a situation like that here, where the producing party committed itself to a search methodology that it chose, and then near the end of the document production that party announced that it would be changing the methodology so that it could evade an obligation to review the documents that it had committed itself to review.

Teva has also relied on *In re Broiler Chicken Antitrust Litig.*, No. 1:16-CV-08637, 2018 WL 1146371 (N.D. Ill. Jan. 3, 2018) claiming that it supports the position that its last second disclosure of unilateral use of TAR layered on a narrowed set of documents established through application of search terms is something that has been approved in

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other cases. Teva cites to this case in the hope of establishing that layering is acceptable, but that case is very different, beginning with the cooperation of the parties up front at the outset. The contrast further demonstrates why Teva's sandbag introduction of TAR is unworkable.

In *Broiler Chicken*, the timing and process by which the parties established the parameters of the Order Regarding Search Methodology for Electronically Stored Information was radically different from what Teva is attempting to do here. First, as is evident from the face of the Order, but also looking at the docket history, the parties negotiated that protocol at the very start of the discovery process, prior to any negotiation of custodians, search terms, etc., all of which occurred in this case last year. Second, that protocol was heavily negotiated and was arrived at with the assistance of an electronic discovery special master appointed by the Court. If Defendants had wanted to do something similar here, they should have approached Plaintiffs more than a year ago. Instead, Teva fully engaged in working to establish a search terms methodology, with the actual search terms negotiations beginning in or about September 2019. Third, the procedure provides a detailed roadmap of how the TAR/CAL process is to be implemented, requiring the parties to work together, with disputes resolved there by the special master. None of that happened here, and none of those safeguards exist here.

Fourth, and most importantly, the procedure provided a detailed roadmap for how search terms are agreed to, including hit counts, sampling, and provision to the requesting party of contextual examples of false positives, all of which Plaintiffs requested Defendants to do in the September to December search term negotiation time frame and which

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Defendants adamantly refused to do. This was discussed during the July 15, 2020 hearing with Plaintiffs' citing to the November 30, 2019 hearing transcript as one of numerous times that Plaintiffs noted Defendants' refusal to run tests and sampling, and work collaboratively with Plaintiffs to utilize the data in constructing the search terms process. In fact, due to time pressures and Defendants' inability to turn data around in a timely fashion, Plaintiffs did not even have access to some of this information, such as the exemplar false positive documents, even during the last round of belated search term renegotiation in 2020.

It is also critical to note that when the parties here were negotiating the *initial* search terms, unlike the case in *Broiler Chicken*, Plaintiffs had no expectation that there was going to be any possibility of further restriction of the corpus of documents to be reviewed using TAR. This holds doubly true for the narrowed search terms agreed to by the parties in June, 2020. Both negotiations would have looked very different if Teva had timely disclosed its intentions, and the parties had a procedure like that in *Broiler Chicken* in place at the beginning of the process.

Therefore, Defendants' reliance on the *Broiler Chicken* case is misplaced, and as with the other cases discussed above, strongly supports Plaintiffs' position. Given that rolling productions are nearing completion, nothing in *Broiler Chicken* supports Defendants' unilateral attempt to inject TAR/CAL as a means to cut off the review or deprive Plaintiffs of documents at this late stage.

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The Documents At Issue Should Be Provided To Plaintiffs

Ultimately, if Teva is to be relieved of its obligation to review “non-responsive” documents, the only fair and workable solution would be for the entire set of allegedly non-responsive documents to be produced to Plaintiffs. Teva has consistently resisted this solution, based on questionable reasoning. To the extent any of the documents are privileged they would likely be identified by a privilege filter, and are subject to clawback. To the extent sensitive information about other products is in the documents that can be redacted per the ESI protocol or presented to the Court in camera for determination. This will save Teva money, and will allow Plaintiffs to ensure that all of the documents are reviewed, which is necessary since even Teva admits that there are at least some relevant documents within the purported “non-responsive” category. This is the outcome supported by the numerous cases cited above, including the Third Circuit’s recent decision on this issue.

Teva Should Be Sanctioned

Teva has drained valuable resources from Plaintiffs’ litigation effort, both in terms of time and expense, including expenses for Plaintiffs’ ESI consultant, which is ongoing. Plaintiffs can never get back the time wasted negotiating a protocol that Teva never implemented, instead cynically withdrawing its motion and setting the groundwork to apply to the Court for relief from its obligation to review all of the search terms documents for production. Teva also wasted an enormous amount of the Court’s time, for weeks working with the parties to try and negotiate an agreed to TAR protocol. As a consequence, the fair outcome is to sanction Teva for the time and financial costs expended by Plaintiffs

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in continually responding to Teva's effort to artificially cut off review and deprive
Plaintiffs of documents.

Respectfully,

A handwritten signature in purple ink, appearing to read "Adam M. Slater", is written over a horizontal line.

Adam M. Slater